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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,058

10/24/2005

Hubert Lochard

3493-0149PUS1

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EXAMINER

VU, JAKE MINH

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

08/04/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/554,058	Applicant(s) LOCHARD ET AL.	
	Examiner Jake M. Vu	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/22/09, 1/24/06, 10/24/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's Restriction Requirement Response filed on 05/18/2009; and Information Disclosure Statements filed on 06/22/2009, 01/24/2006, and 10/24/2005.

- Claims 1-15 are pending in the instant application.
- Claims 11 and 15 are withdrawn from consideration.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-10 and 12-14) and specie election of tiaprofenic agent in the reply filed on 05/18/2009 is acknowledged. The traversal is on the ground(s) that Bernard '867 is distinguished from the method of the present invention as described at pages 4-5 of the present specification. This is not found persuasive because Bernard '867 is not distinguished from Applicant's composition claim. Applicant argues that the number of species disclosed in the present application does not constitute a significant burden on the Examiner. The Examiner finds this argument unpersuasive, because the number of species disclosed in the present application does constitute a burden on the Examiner

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 12-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over copending Application No. 10/594,740 and 10/492,346.

The co-applications teach a method of making a composition comprising of: bringing an active substance (see 10/594,740 at claim 1), such as tiaprofenic acid (see claim 17), into contact with a host molecule, such as cyclodextrin (see claim 26); carrying out a molecular diffusion step by stirring/bringing a dense fluid under pressure, such as CO₂ (see claim 15), in the presence of a diffusion agent, such as water (see claim 19); recovering the molecular complex formed. Additional limitations include: pressure is between 0.5MPa and 50MPa (see claim 18); temperature is between 0 and 200°C (see claim 18).

The references do not specifically teach adjusting the pressure and temperature to 5MPa and 40MPa; 0 and 120°C as claimed by Applicant. The adjustment of the

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pressure and temperature in a method of making is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal pressure and temperature in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of pressure and temperature would have been obvious at the time of Applicant's invention.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what amount is 1-50% and 20-25% by mass. "By mass" of what? Please clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10, 12, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by FREISS et al (WO 03/030867; machine translation included).

Applicant's claims are directed to a method of making a molecular complex comprising of: bringing an active substance, such as tiaprofenic acid, into contact with a host molecule, such as cyclodextrin; carrying out a molecular diffusion step by stirring/bringing a dense fluid under pressure, such as CO₂, in the presence of a diffusion agent, such as water; recovering the molecular complex formed. Additional limitations include: pressure is between 5MPa and 40MPa; temperature is between 0 and 120°C;

FREISS teaches a method of making a molecular complex comprising of: bringing an active substance, such as anilide derivative (see abstract) or piroxicam (see pg. 5 of machine translation), which is an anti-inflammation agent, into contact with a host molecule, such as cyclodextrin (see claim 10 and pg. 25); carrying out a molecular diffusion step (see abstract) by mixing (see pg. 7), which reads on stirring/bringing ,a dense fluid under pressure, such as CO₂ (see pg. 8), in the presence of a diffusion agent, such as water (see pg. 10); recuperating (see abstract), which reads on recovering the molecular complex formed. Additional disclosures include: pressure is between 5MPa and 40MPa (see pg. 11); temperature is between 0 and 120°C (see pg. 11); these steps can be carried out in batch or uninterrupted (see pg. 8).

Note, during the search of the elected species, some non-elected species were found in the search; this is not indicative that a through search of all the species have been done.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over FREISS et al (WO 03/030867; machine translation included) in view of CHOWDHARY et al (US 6,693,093).

As discussed above, FREISS teaches a method of making a molecular complex comprising of: bringing an active substance, such as anilide derivative (see abstract) or piroxicam (see pg. 5 of machine translation), which is an anti-inflammation agent, into contact with a host molecule, such as cyclodextrin (see claim 10 and pg. 25); carrying out a molecular diffusion step (see abstract) by mixing (see pg. 7), which reads on stirring/bringing ,a dense fluid under pressure, such as CO₂ (see pg. 8), in the presence of a diffusion agent, such as water (see pg. 10); recuperating (see abstract), which reads on recovering the molecular complex formed. Additional disclosures include: pressure is between 5MPa and 40MPa (see pg. 11); temperature is between 0 and 120°C (see pg. 11); these steps can be carried out in batch or uninterrupted (see pg. 8).

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FREISS does not specifically teach using an active substance, such as tiaprofenic acid.

CHOWDHARY teaches nonsteroidal anti-inflammatory drugs include piroxicam and tiaprofenic acid (see col. 11, line 33-44).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate tiaprofenic acid into FREISS's method. The person of ordinary skill in the art would have been motivated to make those modifications, because and reasonably would have expected success because tiaprofenic acid and piroxicam are functional equivalents of nonsteroidal anti-inflammatory drugs.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618